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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

CHURCH & DWIGHT CO., INC., a Delaware  
corporation,

Plaintiff,

v.

SPD SWISS PRECISION DIAGNOSTICS  
GmbH, a Swiss Corporation,

Defendant.

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Case No. 14-CV-585 (AJN)

**SPD SWISS PRECISION DIAGNOSTICS,  
GMBH'S REQUEST FOR JUDICIAL  
NOTICE IN SUPPORT OF ITS MOTION  
TO DISMISS**

Hon. Alison J. Nathan  
Trial Date: None Set

Pursuant to Federal Rule of Evidence 201(b), Defendant SPD Swiss Precision Diagnostics GmbH ("SPD") hereby requests that the Court take judicial notice of the facts evidenced by the following documents in support of its Motion to Dismiss under Rule 12(b)(6) filed concurrently herewith:

1. Attached hereto as **Exhibit A** is a true and correct copy of a printout from the U.S. Food and Drug Administration ("FDA") website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.
2. Attached hereto as **Exhibit B** is a true and correct copy of the "Hold Letter" issued by the FDA on September 12, 2012.
3. Attached hereto as **Exhibit C** is a true and correct copy of the FDA Guidance Document that describes FDA procedures when invoking the SE With Limitations process.
4. Attached hereto as **Exhibit D** is a true and correct copy of the FDA's October 18, 2012 response to SPD's proposed labeling for the Weeks Estimator product.
5. Attached hereto as **Exhibit E** is a true and correct copy of the FDA's November 8, 2012 response to SPD's draft of proposed labeling for the Weeks Estimator product.
6. Attached hereto as **Exhibit F** is a true and correct copy of the FDA's November 20, 2012 response, acknowledging submission by SPD labeling for the Weeks Estimator product.
7. Attached hereto as **Exhibit G** is a true and correct copy of the FDA's November 27, 2012 email to SPD stating that "[t]he labeling appears to meet our requests." The email also requests that SPD "prepare your hold response" and include "final labeling."
8. Attached hereto as **Exhibit H** is a true and correct copy of an email from Dr. Lili Duan, a Scientific Reviewer at the FDA to SPD on November 12, 2013.

9. Attached hereto as **Exhibit I** is a true and correct copy of the overall mitigation plan and two alternative drafts of packaging for the Weeks Estimator submitted by SPD to the FDA on November 22, 2013.

**I. Argument**

Under Federal Rule of Evidence 201, courts may take judicial notice of facts that are "not subject to reasonable dispute" because they are: (1) generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.

The documents of which SPD requests the Court take judicial notice, and the facts evidenced by those documents, consist of either internal business records of the FDA, or official correspondence between the FDA and SPD regarding SPD's statutorily-required "510(k)" Application<sup>1</sup> for SPD's Weeks Estimator product. Hence, they constitute facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201.

It is appropriate for a court to judicially notice public documents. *Massachusetts v. Westcott*, 431 U.S. 322, 323, n.2 (1977) (records that could be "ascertained from the records of the Merchant Vessel Documentation Division of the Coast Guard" were properly judicially noticeable). This includes correspondence with a federal agency. *Hein v. Capitan Grande Band of Diegueno Mission Indians*, 201 F.3d 1256, 1259 (9th Cir. 2000) (judicial notice of letter from the National Indian Gaming Commission); *Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889,

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<sup>1</sup> All capitalized terms used in paragraphs 1 through 9 herein have the meaning ascribed to them in SPD's Motion to Dismiss, filed concurrently herewith, unless otherwise noted.

901, n.6 (N.D. Cal. 2012).

In *Jones*, a false advertising case, plaintiff alleged that defendant's labeling of food was false and misleading. In ruling under Rule 12(b)(6) whether to dismiss plaintiff's claims that defendant's products were improperly labeled "natural," the district court took judicial notice of a letter from the FDA to defendant's counsel that stated that naturally-derived citric acid is consistent with labeling a product "natural." *Id.* ("Exhibit E is properly judicially noticeable; it is a letter to Martin J. Hahn at Hogan Lovells U.S. LLP from the FDA"). Likewise, in *Garner v. State Farm Mut. Auto. Ins. Co.*, C 08-1365 CW, 2008 WL 2620900 (N.D. Cal. June 30, 2008), the district court explained that it would be proper to take judicial notice of the fact that the California Department of Motor Vehicles wrote a letter to defendant and of the statements made in that letter because "a Court may take judicial notice of official correspondence from a public agency." *Garner*, 2008 WL 2620900 at \*5.

## **II. Conclusion**

For the foregoing reasons, the Court should take judicial notice of the facts evidenced by the documents set forth above pursuant to Rule 201(b) of the Federal Rules of Evidence.

DATED: March 4, 2014

Respectfully submitted,

By: 

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